

REMARKS:

In response to the Office Action mailed December 16, 2002, new claims 6-16 have been added in order to more particularly claim the subject matter of the present application.

In the Office Action, claims 1, 3, and 4 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,531,788 ("the Dibie et al. reference"). Because the cited reference fails to disclose, teach, or suggest the subject matter of the present claims, the rejections should be withdrawn.

Turning to the Dibie et al. reference, a filter is disclosed that is intended to be installed in a vena cava to prevent clots from migrating into the heart. Col. 1, lines 5-10. The filter is made of a resilient wire, col. 5, lines 60-61, that is shaped as a spiral having three non-touching turns, the middle turn having a diameter that is greater than the dimensions of the other two turns. Col. 6, lines 44-47. The filter is sufficiently resilient and stiff that it stretches or "flattens" the vena cava. Col. 7, lines 6-13. Thus, the Dibie et al. reference merely discloses a stiff wire that is biased to wind into non-touching turns to provide a filter that may be securely mounted within a vena cava.

With respect to the present claims, claim 1 recites a soft flexible helical vasoocclusion coil that includes a proximal end adapted to detachably couple to the distal end of the wire; a distal end; and a multiplicity of windings having a first diameter immediately adjacent the distal and proximal ends. The helical vasoocclusion coil is further wound into a second diameter smaller than the first diameter at the proximal and distal ends, whereby the proximal and distal ends are positioned radially inwardly of the immediately adjacent first diameter such that the coil acts to occlude a vessel or a cavity when placed within the vessel or cavity.

First, the Dibie et al. reference does not disclose, teach or suggest a helical coil that is wound into a multiplicity of windings, as claimed. As explained in Applicants' amendment previously filed on September 22, 1997 (Paper No. 6), this language refers to a "coil of a coil" structure. Paper No. 6, page 4, ¶1. For example, as explained at page 3, lines 16-22 in the specification of the present application, a coil may include windings having a diameter of about 0.01 mm to about 0.50 mm that are wound into a helix having a diameter between about 2.0 to 20 mm. Instead of such a coil of a coil structure, the Dibie et al. reference merely discloses a wire that is wound into non-touching windings.

Second, the Dibie et al. reference does not teach or suggest a soft flexible device, as claimed. The claimed structure is soft and flexible such that it may be placed within a vessel or cavity to occlude the vessel or cavity without injuring or perforating the wall of the vessel or cavity. In contrast, as explained in Paper No. 6, ¶4, the Dibie et al. device is not soft and flexible, but is stiff, acting to stretch the vessel's cross-section to secure the device in the vena cava.

Finally, claim 1 is not obvious over the Dibie et al. reference, because the Dibie et al. reference is intended for a substantially different purpose than the claimed vasoocclusion coil. The Dibie et al. device is a filter that is installed within a vena cava filter to capture clots, but otherwise allow blood to pass freely through the filter into the heart. In contrast, the claimed vasoocclusion coil is intended to occlude a vessel or cavity into which it is placed. The Dibie et al. device is not intended for such purpose, and actually teaches against occluding a vessel. It would be undesirable to occlude the vena cava, which would prevent blood from returning to the heart, and risk substantial injury to a patient receiving the Dibie et al. device. Further, it would be undesirable to use a rigid

device, such as the Dibie et al. filter, as a vasoocclusion coil, because it would risk rupturing a weakened vessel wall, such a wall of an aneurysm being filled. Accordingly, claim 1 and its dependent claim are neither anticipated nor otherwise obvious in light of the Dibie et al. reference.

For similar reasons, claim 4, and claims 6-11 are also neither anticipated nor otherwise obvious in light of the Dibie et al. reference.

Turning to claim 13, a soft flexible helical vasoocclusion coil is recited that includes a proximal end adapted to detachably couple to the distal end of the wire; a distal end; a multiplicity of windings having a first diameter between the proximal and distal ends, the first diameter being between about 0.2 mm and about 30 mm; and the proximal end being wound into a second diameter smaller than the first diameter, whereby the proximal end is positioned radially inwardly of the first diameter such that the coil acts to occlude a vessel or a cavity when placed within the vessel or cavity.

As explained above, the Dibie et al. reference fails to teach or suggest a soft flexible coil, as claimed, but, instead, discloses a stiff coil. In addition, the Dibie et al. reference does not teach or suggest a multiplicity of windings having a diameter between about 0.2 mm and about 30 mm. In contrast, the Dibie et al. reference discloses a wire wound into diameters of 27, 31.5, and 36 mm. Col. 7, lines 13-18. Such sizes are required in order to secure the Dibie et al. device in a vena cava. Col. 6-18. Thus, the Dibie et al. reference fails to disclose, teach, or suggest the sizes recited in claim 13. In fact, the Dibie et al. reference teaches against the claimed range, because such small diameters would not secure the Dibie et al. filter coil within a vena cava, but would release the filter coil freely within a vena cava, where it could move downstream and cause substantial damage to the

patient. Accordingly, claim 13 and its dependent claims are also neither anticipated nor otherwise obvious in light of the Dible et al. reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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Dated: March 17, 2003

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